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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/643,681 | 08/18/2003 | Orville G. Kolterman | 254/057CON | 4614 |

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| EXAMINER | |
|---|---|
| LIU, SUE XU | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1639 | |

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/643,681 | KOLTERMAN ET AL. | |
| | Examiner | Art Unit | |
| | Sue Liu | 1639 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *24-30 and 38-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-30 and 38-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/11/06 has been entered.

### *Claim Status*

Claims 1-23, 31-37, and 60-69 have been cancelled;

Claims 24-30, and 38-59 are currently pending;

Claims 24-30, and 38-59 are being examined in this application.

### *Response to Amendment*

1. Applicant's amendments to the claims and specification dated 4/10/06 are acknowledged.

### *Election/Restriction*

2. Applicant's election with traverse of 25,28,29 tri-pro human amylin as the elected species in the correspondence dated 10/29/04 is again acknowledged and was previously made final.

### *Priority*

3. This application is a CONTINUATION of U.S. Patent Application No. 09/576,062 (filed 5/22/2000), which is now a US PATENT, 6,608,029 (8/19/2003). The U.S. Patent Application No. 09/576,062 is a CONTINUATION of U.S. Patent Application Nos. 08/302,069 (filed 9/7/1994), which is now a US PATENT, 6,114,304 (9/5/2000). The U.S. Patent Application No. 08/302,069 is a CIP of U.S. Patent Application Nos. 08/118,381 (filed 9/7/1993), which is now abandoned.

***Withdrawn Objection (s) and/or Rejection (s)***

4. Upon further consideration, and in view of applicants' response, amendment and affidavit, the following rejections and/or objections are withdrawn:

**A.)** Claims 25-30 and 41-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (NEW MATTER REJECTION). See Page 3 of the Office Action, mailed on 7/8/05.

**B.)** The preliminary amendment filed 8/18/03 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. See Page 21 of the Office Action, mailed on 7/8/05.

**C.)** Claim 24 is rejected to because of the following informalities: line 3: "amount effect" should be --- amount effective ---. Appropriate correction is required. See Page 20 of the Office Action, mailed on 7/8/05.

**D.)** Claims 24 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (Lack of Written Description). See Page 4 of the Office Action, mailed on 7/8/05.

**E.)** Claims 24 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of amylin and specifically disclosed amylin analogues (e.g. specific species of proline containing amylin), the specification does not reasonably provide enablement for the use of amylin agonists which differ from anylin agonist analogues as defined and exemplified in the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use, the invention commensurate in scope with these claims. See Page 8 of the Office Action, mailed on 7/8/05.

**F.)** Claims 24 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al. U.S. Pat. No.6,136,820 (10/2000: filed 12/90 or earlier). See Page 13 of the Office Action, mailed on 7/8/05.

**G.)** Claims 24 and 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al. U.S. Pat. No.6,136,820 (10/2000: filed 12/90 or earlier) or alternatively prima facie obvious in view of Meezan et al. U.S. Pat. No. 5,817,634 (10/98: filed 3/93) for purposes of defining the state of the prior art regarding "diabetes mellitus". See Page 15 of the Office Action, mailed on 7/8/05.

***Outstanding Objection (s) and/or Rejection (s)***

***Double Patenting***

5. Claims 24-30 and 38-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 (especially claims 32-35) of U.S. Patent No. 6,114,304. The previous rejection is maintained for the reasons of record advanced on pages 18 and 19 of the office action mailed on 7/8/2005.

***Discussion***

In response to the above double patenting rejection, applicant has indicated that a terminal disclaimer will be filed, upon withdrawal of all other outstanding rejections and objections. Although applicants state that "applicants disagree with these rejections..." (see pg 19 of applicants' reply filed on 1/11/2006), applicants have not point out the supposed error for the obviousness-type double patent rejection.

Accordingly, the above rejection is hereby maintained.

6. Claims 24-30, 38, 40-57 and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 (especially claims 1-12 and 18) of U.S. Patent No. 6,417,164 . The previous rejection is maintained for the reasons of record advanced on pages 19 and 20 of the office action mailed on 7/8/2005.

***Discussion***

In response to the above double patenting rejection, applicant has indicated that a terminal disclaimer will be filed, upon withdrawal of all other outstanding rejections and objections. Although applicants state that "applicants disagree with these rejections..." (see pg 19 of applicants' reply filed on 1/11/2006), applicants have not point out the supposed error for the obviousness-type double patent rejection.

Accordingly, the above rejection is hereby maintained.

## ***New Rejections***

### *Claim Rejections - 35 USC § 112*

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 25-30, and 41-59 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25-30, and 41-59 recite the limitations "the amylin agonist" and "said amylin agonist". There are insufficient antecedent bases for these limitations in the claims.

### *Claim Rejections - 35 USC § 102*

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Note: the instant claim numbers are in bold font.)

10. Claims 24 and 38-40 are rejected under **35 U.S.C. 102(b)** as being anticipated by Sarantakis et al (US 4,451,394; 05/29/1984).

The present claims are directed to a method of reducing or moderating a postprandial rise in plasma glucose in a mammal comprising administering to said mammal an amylin or an amylin agonist (e.g. claim 24). Claim 38 encompasses mammalian diabetics (e.g. types I or II). "Amylin agonists" "refers to compounds which mimic the effects of amylin" (original specification page 22, lines 3-5: substitute specification page 13-15). One amylin effect encompasses the ability of amylin to reduce post-prandial plasma glucose levels" (e.g. see original specification page 21, lines 6-12: substitute specification page 13, lines 4-8).

Sarantakis et al, throughout the patent, teach methods of treating patients suffering from diabetes mellitus by normalizing post-prandial glucose levels using peptides or polypeptides (see Abstract and col. 1, lines 20+ of the reference), which reads on reducing or moderating a postprandial rise in plasma glucose of **clm 24**. The reference also teaches administrating the dodecapeptides (or peptide with 12 amino acid residues as depicted in col. 1 of the reference) for treatment of diabetes mellitus and normalizing post-prandial glucose in diabetic dogs, rats and humans (patients with diabetes) (see Example 2 of the reference), which reads on administering to mammals with diabetes an amlyin agonist analogue, as recited in **clms 24,** and **38-40**.

The instant specification defines "Amylin agonists" as a term that "refers to compounds which mimic the effects of amylin," and "amylin itself and amylin agonist analogues may also be

referred to broadly as amylin agonist." (original specification page 22, lines 3-5: substitute specification page 13-15). One amylin effect encompasses the ability of amylin to reduce post-prandial plasma glucose levels" (e.g. see original specification page 21, lines 6-12: substitute specification page 13, lines 4-8). Because the dodecapeptide taught by Sarantakis et al mimics the effects of amylin with its ability to reduce post-prandial plasma glucose, the said dodecapeptide reads on an amylin agonist analogue according to the definition recited in the instant specification.

Although the reference does not explicitly teach Type I and Type II diabetes, it is known in the art that diabetes mellitus consists of two subtypes, Type I and II, as evidenced by Meezan et al (US 5,817,643; 10/6/1998; filed on 3/10/1993; previously cited) (see col. 1, lines 25+ of the Meezan reference).

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
6/14/2006

MARK SHIBUYA, PH.D.
PATENT EXAMINER